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Philippe Leferve

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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

02/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/579,919 | Applicant(s) LEFERVE ET AL. | |
| | Examiner DARRYL C. SUTTON | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22 and 24-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 and 24-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed 12/09/2009. New claim 47 has been added. Claim 23 has been canceled.

Applicant's arguments filed 12/09/2009 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Maintained Claim Rejections - 35 USC § 103

Claims 19, 28, 38 and 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Haasmaa et al. (US 2002/0032254) in view of Leusner et al. (US 4,431,800) and further in view of Kim et al. (US 6,123,963); and the rejection is applicable to new claim 47.

Applicant argues that Haasmaa et al. is completely silent about suitable amylose contents; and the list of starches is quite exhaustive, pea starch is one possibility among a large variety of starch sources. The starches used in the examples are barley starches, therefore one of ordinary skill would understand that the best starches for use in the invention are barley starches.

The Examiner disagrees.

As cited by Applicant, pea starch is included on the list of possible starch sources. Therefore, one of ordinary skill in the art would reasonably expect that pea starch would be adequate for use in the invention. The amylose content of the pea starch, and all other starch sources listed, is dependent on their structure, so the inclusion of pea starch as a starch source would reasonably suggest that the amylose content of pea starch is suitable. The Examples are simply possible embodiments of the invention and do not represent the entire scope of the invention.

Applicant argues that Leusner is silent about starch sources; and teaches that hydroxypropylation of starches decreases the tendency towards retrogradation.

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Applicant has shown that decreased retrogradation is often only obtained in combination with high temperature processing, which creates other drawbacks and cites Example 2 of the instant specification.

The Examiner disagrees.

Applicant is claiming hydroxypropylated pea starch as a starch source. It would reasonably be expected that any process to hydroxypropylate the starch of the instant invention would yield an equivalent hydroxypropylated pea starch to those which are hydroxypropylated by the methods of Leusner. In the cited Example, modified amylose-rich corn starch is used as the starch source, not hydroxypropylated pea starch, i.e. legume starch.

Applicant argues that Kim does not teach any film forming composition as presently claimed.

Since the rejection is a 103 obviousness rejection, Kim is not required to teach every element of the claims. As cited in the Non-final office action, Kim et al. teach that conventional processes for coating include coating in a fluidized bed and dip-coating, see page 12. Accordingly, Kim et al. provides motivation for combining it with the Haasmaa et al. and Leusner et al. prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-22, 24-27, 29, 30, 32-38 and 40-43 are rejected under 35 U.S.C.

103(a) as being unpatentable over Lydzinski et al. (US 2003/0099692).

Lydzinski et al. teach oral films comprised of starch which are useful in delivering a variety of agents to produce pharmacological effects (Abstract and [0006]). Starch is intended to include all starches derived from natural sources [0008]. Typical sources of starches are legumes such as peas [0009]. The starch must be modified to achieve the desired film attributes [0010]. Chemically modified products include those which have been hydroxypropylated [0013]. Particularly suitable starches included hydroxypropylated starches [0017]. The starch component also comprises a cellulosic material or a gum, including hydroxyalkylcelluloses, microcrystalline cellulose, carrageenan, alginates or pullulan in amounts of less than 15% [0022]. The starch is present in amounts ranging from about 50 to about 100% [0023]. At least one plasticizer may be added to increase the apparent flexibility of the films, including polyols, such as propylene glycol, sugar alcohols such as sorbitol or polyesters such as triethyl citrate in amounts from 0 to about 15% [0026]. The film may be made by a variety of processes known in the art; films may be formed by shaping into a solidified form by any technique known in the art, including wet casting, and extrusion molding; the solution may also be directly coated or sprayed onto another product such as a tablet and dried to form a film [0029]. A particular suitable process for preparing films is by making a solution of film components, applying the starch solution to a substrate,

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drying the coated substrate and removing the film from the substrate [0030].

Conventional coating processes, i.e. processes known in the art, include coating in a fluidized bed and dip-coating.¹

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables stabilized starch, plasticizer, secondary film forming agent and additional agents anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of

¹ Kim et al. US 6,123,963, column 6, lines 58-60.

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ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007).

The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients hydroxypropylated pea starch; sorbitol or triethyl citrate; cellulosic materials, alginates, carrageen or pullulan; and microcrystalline cellulose from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

In regards to claims 29, 30, 32-34 and 41-43, the prior art does not specifically teach a pulverulent composition. However, the starch and the secondary film forming agent are in a dry form, i.e. powders or granules. It would be well within the purview of the skilled artisan to combine the two components to form a pulverulent composition to which the other components are added.

In regards to claims 29, 30, 33 and 42, the prior art does not teach the specific weight percentages of the hydroxypropylated starch or of the secondary film-forming agent; or the weight percentage of the plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15 to 75% of instant claims 29 and 30; that the starch

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component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claims 29 and 30; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claims 33 and 42.

In regards to claims 32 and 41, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claims 32 and 41.

In regards to claim 35, since the composition of the prior art are comprised of substantially the same components as those of the instant claim, it would reasonably be expected to exhibit substantially the same viscosity as the instant invention.

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Claims 31 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lydzinski et al. as applied to claims 19-22, 24-27, 29, 30, 32-38 and 40-43 above, and further in view of Fuertes et al. (US 6,469,161).

Lydzinski et al. are discussed above.

Lydzinski et al. do not teach a hydroxypropylated and fluidification-treated pea starch.

Fuertes et al. teach a fluidification process for starchy materials (Abstract). Fluidification techniques can be combined with other types of modification, in particular with etherification reactions. Common properties obtained include increased film strength (column 2, lines 33-45). A fluidification stage can be preceded by other chemical modifications, such as hydroxypropylation reactions (column 3, lines 1-10, column 6, lines 53-67 and column 8, lines 39-55). Starchy materials of every origin and nature can undergo the fluidification process (column 5, lines 30-34). Starchy material is understood to be all modified starches resulting from chemical modification of native starches; particularly pea starch (column 7, lines 1-10). Chemical modifications include known techniques such as etherification, particularly hydroxyalkylation (column 7, lines 24-39). The process constitutes a new, particularly straightforward, inexpensive and high performance method of obtaining converted, notably fluidified/hydroxypropylated, starchy materials. The industrial sectors concerned with starchy materials complying with the instant invention include the food and pharmaceutical industries (column 10, lines 3-16).

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Fuertes et al. do not teach a composition specifically comprised of pea starch and an amount of secondary film-forming agent; or the amounts of each; or a composition comprised of pea starch and an amount of secondary film-forming agent further comprised of 1 to 20% of microcrystalline cellulose; or further comprised of a from 5-15% of plasticizer.

At the time of the invention, it would have been obvious to modify the hydroxypropylated pea starch of Lydzinski et al. with the methods of Fuertes et al. to inexpensively produce a hydroxypropylated and fluidification-treated starchy material with increased film strength for use in the pharmaceutical industry, i.e., in preparing pharmaceutical compositions, as taught by Fuertes et al.

The prior art does not teach the specific weight percentages of the hydroxypropylated starch or of the secondary film-forming agent; or the amount of plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15 to 75% of instant claim 31; that the starch component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claim 31; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claim 45.

In regards to claim 44, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie*

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obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claim 44.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612